naphthyl-C_1 - C_8 while claims 28 and 29 do not include this group for R^1, R_2, R_3, R_4 and R_6. Claim 29 also differs from claim 1 in this regard and also differs from claim 28 in the definition of W which in the case of claim 28 does not include C_1-$_8$ alkylamino. These claims are not duplicate claims because they are not merely different in wording but they differ in scope. For these reasons, it is requested that this ground of objection be withdrawn.

The spelling of --camphane-- in claim 1 has been corrected.

Claims 1-3, 10 and 27-29 have been rejected under 35 U.S.C.§112, first paragraph, for failing to comply with the written description requirement. The Examiner noted that the rejection was based on the contention that the manner of making the claimed esters was not disclosed, that there was an insufficient description of the method of inhibiting 5-alpha reductase and the treatment of the diseases identified in claim 27 and an insufficient description of "fully and partially reduced" in line 1 of claim.

Reconsideration is requested.

The term esters" has been deleted from claims 1, 28 and 29. In addition, the term "fully and partially reduced" has been deleted from claims 1, 28 and 29.

The text of claim 27 points out a method for the inhibition of 5 alpha reductase- and or 5 alpha reductase-II iso-enzyme. The claim also specifies five specific disease states that are well known to respond to treatment with 5α reductase inhibitors. The specifiaction, at page 18, provides test data that shows that compounds disclosed by the applicants have the ability to inhibit 5α reductase. This is set forth at pages 18 and 19 of the specification. It is well known that compounds which inhibit 5α reductase are useful for treating prostatic hypertrophy, prostate cancer, acne, male pattern baldness and hirsutism. See claim 9 in U.S. 5,543,406 which is of record in the present applciation.

The present specification at pages 2 and 3 lists a number of conditions that are caused byt the action of 5-alpha reductase and points out that the selectivity of the compounds

of the invention for inhibition these enzymes makes the compounds useful for treating baldness in men, hirsutisnm in women and itions caused by 5-alpha reductase. Reference to known compounds for inhibiting 5-alpha reductase these pathologies as a basis for using these compounds is made at pages 8 and 19 of the specification. Under the rule from Cross v Ituka, 224 USPQ 738 (Fed. Cir 1985), the present disclosure is in compliance with 35 U.S.C.§112, first paragraph. With regard to In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988), the Examiner is asked to consider that the Wands decision involved a situation where nine of 143 disclosed cell lines were made and tested. Of the nine cell lines, 4 were found to have the high affinity and IgM serotype according to the Wands invention. This was held by the Wands court to be a disclosure that did not require undue experimentation and was therefore enabling. In the present case, the chemical compounds are related and no showing has been made that there is such a degree of unpredictability that one skilled in the art would expect that it would not be possible to practice the claimed invention without undue experimentation. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 1, 3, 27, 28 and 29 were rejected under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

Reconsideration is requested.

The term "A compound" is not made indefinite by the recitation of "and its salts". This terminology defines a finite and ascertainable group of compounds which is not open ended. This is what is required by the second paragraph of 35 U.S.C.§112. The term "salts" is a broad and well known term to those who are skilled in the art and merely because it is generic in scope it is not indefinite.

The claims have been amended to insert the definition of R and R' where necessary. Claim 3 has been amended to recite the benzo[c]quinolizine in the singular. A proper antecedent basis for the subject matter of claim 3 has been added by

reference to claim 1. Claim 27 has been modified to point out a method of treatment by reference to an afflicted host. As noted above, the term "fully or partially reduced" has been deleted from the claims. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 1, 2, 28 and 29were rejected unbder 35 U.S.C.§102(b) as being anticipated by Acheson et al.

Reconsideration is requested.

The Acheson et al. reference is concerned with a benzoquinolizine compound and not with a partial or fully saturated compound as defined by the claims of the present application. The argument, that the benzoquinolizine compound 8 of Acheson et al. may be reduced to yield the instantly claimed compound, is not a basis for rejecting the claimed compounds as anticipated by the Acheson et al. reference as the Acheson et al. reference does not disclosed a partially or fully reduced compound. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 1, 3, 28 and 29 were rejected under 35 U.S.C.§103 as being unpatentable over Guarna et al. (WO9905913) in view of Guarna (J. Med. Chem 1997, Vol. 40 p.1197) and Strandtmann et al.

Reconsideration is requested.

The Guarna et al. (WO9905913) published application was pubblished on February 11, 1999 and it is the application of the inventors of the present application, Since the present application claims an effective filing date of December 21, 1998, the Guarna et al.(WO9905913) published application is not prior art to the present application. The Guarna publication is concerned with azasteroids and not with partially or completely saturatyed benzoquinolizines. Strandtmann et al. are concerned with unsaturated benzoquinolizines which do not suggest the preparation of partially or fully saturated benzoquinolizines according to the present invention. For these reasons, it is requested that this ground of rejection be withdrawn.

A terminal disclaimer is attached to this Amendment which obviates the rejection for double patenting.

Authorization is given to charge Deposit Account 08-1540 for the required fee for filing a terminal disclaimer.

An early and favorable action is earnestly solicited.

Respectfully submitted,

James V. Costigan
Reg. No. 25,669

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036-2601
(212) 302-8989

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 on 10/27/04